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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,564	04/21/2004	Peter M. Palese	PP26000US	5866

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EXAMINER	
CHEN, STACY BROWN	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 06/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/828,564	PALESE ET AL.	
	Examiner	Art Unit	
	Stacy B. Chen	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 April 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-61* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-61* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 2, drawn to an isolated paramyxovirus comprising SEQ ID NO: 9, 10, 11, 12, 13 and 14, classified in class 424, subclass 211.1.

II. Claims 3-5, 43 and 44, drawn to an isolated paramyxovirus, classified in class 424, subclass 211.1. Further restriction is required if Group II is elected. Applicant is required to elect one identifying characteristic selected from the following:

A. a nucleic acid molecule hybridizing to SEQ ID NO: 3.

B. a nucleic acid molecule hybridizing to SEQ ID NO: 7.

C. a nucleic acid molecule hybridizing to SEQ ID NO: 8.

D. a nucleic acid sequence having at least 90% identity with SEQ ID NO: 3.

E. a nucleic acid sequence having at least 90% identity with SEQ ID NO: 7.

F. a nucleic acid sequence having at least 90% identity with SEQ ID NO: 8.

G. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 9.

H. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 10.

I. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 11.

J. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 12.

K. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 13.

L. a nucleic acid sequence encoding a polypeptide having SEQ ID NO: 14.

M. a polypeptide having at least 90% identity with SEQ ID NO: 9.

N. a polypeptide having at least 90% identity with SEQ ID NO: 10.

O. a polypeptide having at least 90% identity with SEQ ID NO: 11.

P. a polypeptide having at least 90% identity with SEQ ID NO: 12.

Q. a polypeptide having at least 90% identity with SEQ ID NO: 13.

R. a polypeptide having at least 90% identity with SEQ ID NO: 14.

(*All of A-R are classified in class 424, subclass 211.1.*)

III. Claims 6, 7 and 40, drawn to an isolated antibody, classified in class 424, subclass 130.1. Further restriction is required if Group III is elected. Applicant is required to elect one sequence to which the antibody binds, selected from A-R, outlined above. *(All antibodies that bind to an epitope on the paramyxoviruses A-R are classified in class 424, subclass 130.1.)*

IV. Claims 8-12 and 39, drawn to an isolated polynucleotide encoding polypeptides comprising SEQ ID NO: 9, 10, 11, 12, 13 and 14, classified in class 536, subclass 23.72.

V. Claims 13 and 14, drawn to an isolated polynucleotide, classified in class 536, subclass 23.72. Further restriction is required if Group V is elected. Applicant must elect one polypeptide sequence for examination, selected from the following list:

AA. SEQ ID NO: 9.

BB. SEQ ID NO: 10.

CC. SEQ ID NO: 11.

DD. SEQ ID NO: 12.

EE. SEQ ID NO: 13.

FF. SEQ ID NO: 14.

(All polynucleotides encoding AA-FF are classified in class 536, subclass 23.72.)

VI. Claims 15-26, 41 and 55-58, drawn to an isolated polypeptide, classified in class 530, subclass 300. Further restriction is required if Group VI is elected. Applicant must elect one polypeptide sequence for examination, selected from AA-FF, outlined above. Appropriate claims will be examined with the elected sequence. *(All polypeptides of AA-FF are classified in class 530, subclass 300.)*

VII. Claims 27 and 28, drawn to a method for detecting a Chris-like virus comprising contacting a virus particle with an antibody, classified in class 435, subclass 7.1. Further restriction is required if Group VII is elected. Applicant is required to elect one sequence to which the antibody binds, selected from A-R, outlined above. *(All methods encompassing A-R are classified in class 435, subclass 7.1.)*

VIII. Claims 29-35, drawn to a method for detecting the presence or absence of a Chris-like virus comprising contacting a nucleic acid molecule from a sample with at least one primer or probe, classified in class 435, subclass 6.

IX. Claims 36-38 and 42, drawn to an agent that modulates the replication of paramyxovirus, classified in class 424, subclass 184.1. Further restriction is required if Group IX is elected. Applicant is required to elect one type of agent, selected from the following:

AAA. Peptide and peptide analog, classified in class 530, subclass 300.

BBB. Polynucleotide and small interfering RNA, classified in class 536, subclass 23.1.

CCC. Ribozyme, classified in class 424, subclass 184.1.

X. Claim 45, drawn to a method of treating or preventing a viral infection by administering an agent that modulates the replication of paramyxovirus, classified in class 435, subclass 5. Further restriction is required if Group X is elected. Applicant is required to elect one type of agent, selected from AAA-CCC, outlined above.

XI. Claim 46, drawn to a method of inhibiting replication of a paramyxovirus comprising administering an antibody, classified in class 435, subclass 7.1. Further restriction is required if Group XI is elected. Applicant is required to elect one sequence to which the antibody binds, selected from A-R, outlined above. *(All methods encompassing A-R are classified in class 435, subclass 7.1.)*

XII. Claim 47, drawn to a method of inhibiting replication of a paramyxovirus comprising administering to a subject a polypeptide, classified in class 435, subclass 5. Further restriction is required if Group XII is elected. Applicant must elect one polypeptide sequence for examination, selected from AA-FF, outlined above. Appropriate claims will be examined with the elected sequence. *(All methods encompassing polypeptides of AA-FF are classified in class 435, subclass 5.)*

XIII. Claim 48, drawn to a method of modulating tumor growth by administering a paramyxovirus, classified in class 435, subclass 5.

XIV. Claim 49, drawn to a method for identifying an agent effective for modulating replication of paramyxovirus, classified in class 435, subclass 5. Further restriction is required if Group XIV is elected. Applicant is required to elect one type of agent, selected from AAA-CCC, outlined above.

XV. Claims 50-54, drawn to a kit comprising at least one primer or probe, classified in class 536, subclass 24.3.

XVI. Claims 59-61, drawn to a nucleic acid molecule comprising a Chris-like virus nucleic acid sequence operably linked to a heterologous nucleic acid sequence encoding a heterologous protein, classified in class 536, subclass, 23.4.

The inventions are distinct, each from the other because of the following reasons:

a) Inventions I and II are directed to related paramyxoviruses. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the paramyxovirus of Group I contains polypeptides SEQ ID NO: 9-14. The viruses of Group II contains, SEQ ID NO: 9, or 10, or 11, or 12, or 13 or 14. A virus of Group I and a virus of Group II are not comprised of the same polypeptides because the virus of Group I has all of the claimed sequences, whereas the virus of Group II contains only one of the claimed sequences. A search for the viruses of Group I and Group II would be a serious burden.

b) Inventions A-R are drawn to paramyxoviruses having different identifying characteristics. A virus from Group A is not a virus from Group B, etc. The viruses are

comprised of different polypeptides/polynucleotides. A search for all of the viruses of A-R would be a serious burden.

c) Inventions (I-II) and (III) are directed to distinct inventions. While the inventions of both Groups are composed of polypeptides, in this instance the polypeptides of Groups I and II form a complex viral structure that acts as an intracellular parasite, whereas the polypeptide of Group III encompasses antibodies including IgG which comprises 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs) that function to bind an epitope. Thus the viruses and antibodies are structurally distinct molecules; any relationship between a virus and an antibody is dependent upon the correlation between the scope of the polypeptides that the antibody binds and the scope of the antibodies that would be generated upon immunization with the polypeptide.

In this case, viruses contain potentially hundreds of regions to which an antibody may bind, whereas the antibody of Group III is defined in terms of its binding specificity to a small structure within a certain sequence. Thus immunization with the viruses of Groups I and II would result in the production of antibodies outside the scope of Group III (i.e., antibodies that bind to regions other than the claimed sequences). Therefore the polypeptide and antibody are patentably distinct.

Furthermore, searching the inventions of Groups (I and II) and III would impose a serious search burden. The inventions have a separate status in the art as shown by their different classifications. A polypeptide and an antibody which binds to the polypeptide require different searches. An amino acid sequence search of the full-length protein is necessary for a

determination of novelty and unobviousness of the protein. However, such a search is not required to identify the antibodies of Group III. Furthermore, antibodies which bind to an epitope of a virus of Groups I and II may be known even if an antibody of Group III is novel. In addition, the technical literature search for viruses and the antibody of Group III are not coextensive, e.g., antibodies may be characterized in the technical literature prior to discovery of or sequence of their binding target.

d) The antibodies that bind to A-R are all distinct products. Each antibody binds to a different sequence having different epitopes and thus different paratopes. A search for one antibody is not likely to reveal the others. A search for all the antibodies would be a serious burden.

e) Groups IV and V are drawn to distinct polynucleotides. The nucleic acid of Group IV encodes polypeptides SEQ ID NO: 9-14. The sequences of Group V encode SEQ ID NO: 9, or 10, or 11, or 12, or 13 or 14. The polynucleotide of Group IV and V are not comprised of the same nucleic acids because the polynucleotide of Group I encodes all of the claimed sequences, whereas the polynucleotides of Group II encode only one of the claimed sequences. A search for the polynucleotides of Groups IV and V would be a serious burden.

f) Groups (IV and V), XV, IX and XVI are drawn to distinct inventions. The nucleic acid of Groups IV and V encodes viral proteins. The nucleic acid of Group XVI encodes a virus with a heterologous protein. The nucleic acid of Group IX is an agent that modulates the replication of a paramyxovirus. The nucleic acid of Group XV is a primer or probe for hybridization. The sequences of Groups (IV and V) and XVI encode different products, proteins and viruses, each

having different structures and 3D conformations. The modulating agent is not a viral polynucleotide. A search for all of these sequences would be a serious burden.

g) Groups (I and II) and (IV, V, XV, IX and XVI) are drawn to distinct products. The viruses of Groups I and II and polynucleotides of Groups IV, V, XV, IX and XVI are patentably distinct inventions for the following reasons. Viruses are composed of polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide does not necessarily encode a polypeptide of a virus. For example, complementary sequences are claimed which do not encode the claimed viruses. Sequences having 90% percent homology will not encode the same polypeptides as those claimed in the virus. A nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO. 9. In addition, while a virus of Groups I and II can made by methods using some, but not all, of the polynucleotides that fall within the scope of Groups IV V and XVI, it can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions are patentably distinct.

Furthermore, searching the inventions together would impose a serious search burden. In the instant case, the search of the viruses/polypeptides and the polynucleotides are not

coextensive. The inventions of Groups have a separate status in the art as shown by their different classifications. In cases such as this one where descriptive sequence information is provided, the sequences are searched in appropriate databases. There is search burden also in the non-patent literature. Prior to the concomitant isolation and expression of the sequence of interest there may be journal articles devoted solely to polypeptides which would not have described the polynucleotide. Similarly, there may have been "classical" genetics papers which had no knowledge of the polypeptide but spoke to the gene. Searching, therefore is not coextensive. As such, it would be burdensome to search the inventions of Groups I and II together.

h) The polynucleotides of Groups (IV, V, XV, IX and XVI) and the antibody of Group III are patentably distinct for the following reasons. The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides, such as the antibody of Group II which are composed of amino acids, and polynucleotides, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Groups (IV, V, XV, IX and XVI) will not encode an antibody of Group III, and the antibody of Group III cannot be encoded by a polynucleotide of Groups (IV, V, XV, IX and XVI). Therefore the antibody and polynucleotide are patentably distinct.

The antibody and polynucleotide inventions have a separate status in the art as shown by their different classifications. Furthermore, searching both inventions would impose a serious search burden since a search of the polynucleotides would not be used to determine the patentability of an antibody of Group III, and vice-versa.

i) The polypeptides represented by SEQ ID NO: 9-14 are all distinct products. The sequences SEQ ID NO: 9, 10, 11, 12, 13 and 14 are not identical, each requiring a separate search. Further, the polypeptides assemble into different proteins that do not share function or effect. A search for each sequence would be a serious burden.

j) The viruses of Groups (I and II) and the polypeptides of Group VI are drawn to distinct products. Viruses are comprised of polypeptides that assemble into different proteins. Viruses are complex structures that function as intracellular parasites. Polypeptides that make up the viruses are distinct structures, a single chain of amino acids. A search for viruses and its polypeptides would be a serious burden because the viruses may have been known in the literature prior to the characterization its proteins and polypeptides.

k) The antibodies of Group III and the polypeptides of Group VI are distinct products. While the antibodies may bind to an epitope on polypeptides, the structures of the antibodies and polypeptides are distinct. The antibody of Group III includes, for example, IgG molecules which comprise 2 heavy and 2 light chains containing constant and variable regions, and including framework regions which act as a scaffold for the 6 complementarity determining regions (CDRs). Polypeptides are composed of a single chain of amino acids. These structures are not the same either in amino acid content or structure. Further, searching the antibodies and

polypeptides would be a serious burden because the polypeptides may have been known in the literature prior to the characterization of their binding partners (polypeptides).

l) The polynucleotides of Groups (IV and V) and the polypeptides Group VI are patentably distinct inventions for the following reasons. Polypeptides, which are composed of amino acids, and polynucleotides, which are composed of purine and pyrimidine units, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by the nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, the claimed polynucleotides do not necessarily encode the claimed polypeptides. For example, nucleic acid molecules include complements that hybridize. These polynucleotides do not encode the claimed polypeptides. Furthermore, the information provided by the polynucleotides can be used to make a materially different polypeptide than those claimed. For example, a nucleic acid which hybridizes to SEQ ID NO: 1, even under stringent conditions, encompasses molecules which contain point mutations, splice sites, frameshift mutations or stop codons which would result in use of a different open reading frame, and thus encode a protein that lacks any significant structure in common with SEQ ID NO: 9. In addition, while a polypeptides can made by methods using some, but not all, of the claimed polynucleotides, they can also be recovered from a natural source using by biochemical means. For instance, the polypeptide can be isolated using affinity chromatography. For these reasons, the inventions of are patentably distinct.

m) The methods of Groups VII, VIII, X, XI, XII and XIII are all distinct. Methods of detecting a virus with an antibody versus a nucleic acid molecule are distinct because the

methods use different reagents and method steps. A search for one will not necessarily reveal the other. Methods of treating or preventing a viral infection by administering an agent, an antibody, a polypeptide, and a virus are distinct because the methods use different reagents and method steps. A search for one will not necessarily reveal the other. Searching all of the claimed methods would be a serious burden.

n) Inventions II and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the viruses can be used to purify antibodies on a column.

o) Inventions III and VII are related as product and process of use. In this case, the antibodies can be used in a materially different method, such as in a method of inducing passive immunity.

p) Inventions (IV and V) and VIII are related as product and process of use. In this case, the polynucleotides can be used in a method of inducing an immune response.

q) Inventions VI and XII are related as product and process of use. In this case, the polypeptides can be used in a method of epitope mapping.

r) Inventions IX and XIV are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make another and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the agent can be purified from its natural source.

Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention. The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Should Applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Conclusion

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications

may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stacy B. Chen whose telephone number is 571-272-0896. The examiner can normally be reached on M-F (7:00-4:30). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Stacy B. Chen 5/30/06
Stacy B. Chen
Primary Examiner
May 30, 2006